

Remarks

Claims 70-87 are pending in the subject application. Applicants acknowledge that claim 78 has been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 70, 72, 74, 76, 79, 82, 84 and 86 and added new claims 88-91. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, pages 26-32 of the as-filed specification and original claims 1-15). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 70-91 are currently before the Examiner and read on the elected invention and species. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 102(e) (over Velardi *et al.*).

Claims 70-77, 79 and 81-87 are rejected under 35 U.S.C. § 102(e) as anticipated by Velardi *et al.* (U.S. Published Application No. 2005/0037002). The Office Action indicates that the Velardi *et al.* reference discloses making antibodies or fragments (such as human, humanized, chimeric, and fragments of these such as Fab or Fab'2) thereof that block the KIR2DL receptors of NK cells by: (1) immunizing a non-human mammal, including a mouse, rat, bovine, porcine, horse, rabbit, goat, sheep or XENOMOUSE, with an immunogen comprising a KIR2DL polypeptide, including one on the surface of an NK cell, (2) preparing monoclonal antibodies from the said immunized animal, wherein said monoclonal antibodies bind said KIR2DL polypeptide, (3) selecting monoclonal antibodies from step (2) that cross react with at least two different serotypes of KIR2DL polypeptides, and (4) selecting monoclonal antibodies of (3) that inhibit KIR2DL-mediated inhibition of NK cells, such as KIR2DL-mediated inhibition of NK cytotoxicity, and additionally selecting and isolating an antibody that binds to a human (*i.e.*, a primate) NK cell and to KIR2DL1 and KIR2DL2/3. The Office Action also indicates that the Velardi *et al.* reference discloses that the antibodies preferably bind a common determinant of KIR2DL human receptors such as KIR2DL1 and KIR2DL2/3, and that the monoclonal antibody is DF200, binds to the same epitope as DF200 or competes for binding with DF200. The Office Action contends that Velardi *et al.* disclose that the antibody may be an antigen-binding fragment of one of the aforementioned antibodies and that the

antibody used for therapy may have a human or non-human primate IgG1 or IgG3 Fc portion. Finally, Velardi *et al.* is cited as disclosing that the inhibitory antibody (such as DF200) or a fragment thereof may be administered with a therapeutic antibody in order to treat cancer by enhancing ADCC of the therapeutic antibody. Applicants respectfully assert that the Velardi *et al.* reference does not anticipate the claimed invention. Applicants respectfully submit that Velardi *et al.* is not prior art to the claimed invention as the claims are entitled to the benefit of the filing date of 60/483,894 (filed July 2, 2003). Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e) is respectfully requested.

Claims 70-77 and 79-87 are rejected under 35 U.S.C. § 103(a) as obvious over Velardi *et al.* (U.S. Published Application No. 2005/0037002) in view of Eisenthal *et al.* (1990). The Office Action claims that Eisenthal *et al.* teach that administration of appropriate cytokines such as IL-2 may be a useful adjunct to the administration of mAb for the treatment of cancer in humans, by increasing ADCC, including that mediated by NK cells. The Office Action states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have included IL-2 as taught by Eisenthal *et al.* in the antibody composition taught by Velardi *et al.* Applicants respectfully assert that the claimed invention is not obvious over the cited references. As noted above, Velardi *et al.* is not prior art to the claimed invention; thus, a *prima facie* case of obviousness has not been established for the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

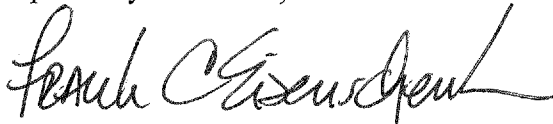
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/jb